

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

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| UNITED STATES OF AMERICA, |) | |
| |) | |
| Plaintiff, |) | |
| |) | |
| v. |) | No. 4:21-CV-437 RLW |
| |) | |
| ERIC ANTHONY NEPUTE, et al., |) | |
| |) | |
| Defendants. |) | |

MEMORANDUM AND ORDER

The United States of America (“Plaintiff” or “Government”) brings this enforcement action against Defendants Eric Anthony Nepute and Quickwork, LLC (“Quickwork”) for alleged deceptive advertising of dietary supplements in violation of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. §§ 45(a) and 52, and the COVID-19 Consumer Protection Act (“COVID-19 Act”), Pub. L. No. 116-260, Title XIV, § 1401. The matter is before the Court on Plaintiff’s Motion for Partial Summary Judgment as to liability for 12,859,355 violations of the FTC Act and 10,175,234 violations of the COVID-19 Act. (ECF No. 94). In addition, Plaintiff seeks to limit or exclude three of Defendant Nepute’s disclosed experts. (ECF No. 78). Also before the Court is Defendant Nepute’s Motion for Partial Summary Judgment as to civil penalties. (ECF No. 82). The motions are fully briefed and ripe for review. For the reasons that follow, Plaintiff’s Partial Motion for Summary Judgment is granted in part and denied in part, Plaintiff’s Motion to Exclude Defendant Nepute’s Experts is granted, and Defendant Nepute’s Motion for Partial Summary Judgment is denied.

I. Factual and Procedural Background

Defendant Nepute is a chiropractor and a member and co-manager of Quickwork.¹ Defendant Nepute and Quickwork publicly market and sell vitamins and supplements nationwide under the trade name “Wellness Warrior.” Since early 2020, Defendant Nepute and Quickwork have used several platforms, including social media, emails, and radio, to tout the purported benefits of Vitamin D and zinc and to promote Wellness Warrior supplements.

On April 15, 2021, the Government filed this cause of action against Defendant Nepute and Quickwork. The Government alleges Nepute has made false and misleading claims about Wellness Warrior supplements, including that Wellness Warrior supplements containing Vitamin D and/or zinc are effective for the treatment, cure, prevention, or mitigation of coronavirus disease 2019 (“COVID-19”), and that they provide equal or better protection against COVID-19 than available vaccines. (ECF No. 1 at 20-21). The Government alleges Defendant Nepute’s claims are false or misleading in that there is no competent and reliable scientific evidence that either Vitamin D or zinc protects against, treats, or prevents COVID-19. The Government further asserts there is no competent and reliable scientific evidence that Vitamin D or zinc, administered independently or in combination, is a better option for prevention of treatment of COVID-19 than the available vaccines. Plaintiff alleges Defendant Nepute lacked any reasonable bases for the claims he made about the efficacy of Vitamin D and zinc for treating and preventing COVID-19. The Government alleges these claims, among others, were made in the context of advertising

¹The Government and Quickwork entered into a consent judgment, and on November 14, 2022, the Court issued a Stipulated Order for Permanent Injunction and Civil Penalty Judgment, pursuant to which Quickwork is enjoined from making certain express or implied representations about its supplements. (ECF No. 115 at 4-5). Judgment was entered against Quickwork in the amount of One Million Dollars (\$1,000,000.00) as a civil penalty. Quickwork is no longer a party to this action.

Wellness Warrior supplements. The Government alleges Defendant Nepute's advertising has been very popular, and his videos have been viewed millions of times. Plaintiff further alleges Defendant Nepute has earned a substantial amount of money from selling Wellness Warrior products.

Plaintiff brings two counts against Defendant Nepute. Plaintiff alleges Defendant Nepute's statements made in connection with the advertisement and sale of Vitamin D and zinc supplements constitute "unfair or deceptive acts or practices" in violation of Sections 5(a) and 12 of the FTC Act (Count I); and that they violate Section (b) of the COVID-19 Act (Count II). For relief, the Government seeks a permanent injunction; an award of damages, including for rescission or reformation of contracts, the refund of monies paid, restitution, and the disgorgement of ill-gotten monies; civil penalties for each violation of the COVID-19 Act; and costs.²

² Contemporaneously with the Complaint, Plaintiff filed a motion for preliminary injunction. Shortly thereafter, however, the parties filed a Joint Motion for Entry of Consent Order, which the Court granted. The Consent Order prohibits Defendant Nepute from:

A. In connection with the advertising of Wellness Warrior Products . . . making, directly or indirectly, expressly or impliedly, any representations concerning the use of such products to cure, mitigate, protect against, treat, or prevent COVID-19, including but not limited to the following representations:

1. Vitamin D or zinc, including Wellness Warrior Products containing Vitamin D or zinc, may be used to cure, mitigate, treat, or prevent COVID-19;
2. That Vitamin D and zinc, including Wellness Warrior Products containing Vitamin D or zinc, are scientifically proven to treat or prevent COVID-19 (including that there is any scientifically proven biological mechanism by which Vitamin D or zinc can effectively treat or prevent COVID-19);
3. That people who have enough Vitamin D or zinc, including Wellness Warrior products containing Vitamin D or zinc, have a lower risk of catching COVID-19 or dying from COVID-19 than people who are deficient;

Following discovery in this case, Plaintiff filed a motion pursuant to Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), to limit or exclude the testimony of Defendant Nepute's three experts. Plaintiff argues two of Defendant Nepute's experts should be excluded entirely because they are not qualified to offer expert testimony in this case. The Government also moves to exclude expert testimony regarding whether Defendant Nepute made misleading statements.

4. That there are studies that show that people who have enough Vitamin D, including Wellness Warrior Products containing Vitamin D, have a 52 percent lower risk of dying of COVID-19 than people who are deficient;

5. That scientific research concluded that people who have enough Vitamin D, including Wellness Warrior Products containing Vitamin D, are 54 percent less likely to catch COVID-19; or

6. That scientific publications indicate that people who have enough vitamin D, including Wellness Warrior Products containing Vitamin D, are 77 percent less likely to catch COVID-19.

B. In connection with the advertising of Wellness Warrior Products (including but not limited to Wellness Warrior Vitamin D, Wellness Warrior Zinc, Wellness Warrior Kids' Multivitamin, Wellness Warrior Boost Pack, and Wellness Warrior Immune Pack, or any nutritional supplements sold or advertised by Defendants), making, directly or indirectly, expressly or impliedly, any representations that such products provide equal or better protection against COVID-19 than do currently available vaccines.

(ECF No. 15 at 2-4).

On November 22, 2022, on Plaintiff's motion, the Court ordered Defendant Nepute to appear and show cause why he should not be held in contempt for his failure to comply with the Consent Order. On December 19, 2022, the parties informed the Court that they had reached an agreement. The parties filed a joint proposed order, which the Court signed, wherein Defendant Nepute was ordered, among other things, to remove recordings of the daily radio show "Real Talk with Dr. Eric Nepute" from websites and media that the defendants control that contain statements prohibited by the Consent Order, including shows dated February 4, 2022, February 7, 2022, February 15, 2022, February 16, 2022, February 17, 2022, and February 21, 2022. (ECF No. 138).

The Government also moved for partial summary judgment. Plaintiff asks that the Court find: (1) Defendant Nepute's publications are "advertisements" within the meaning of the FTC Act; (2) Defendant Nepute's advertisements are misleading, false, and unsubstantiated in that (a) Vitamin D and zinc do not provide equal or better protection against COVID-19 than available vaccines, and (b) zinc is not effective for treating and preventing COVID-19; (3) Defendant Nepute is individually liable for Quickwork's deceptive claims; and (4) Defendant Nepute is liable for civil penalties for 10,175,234 violations of the COVID-19 Act. The Government is not moving for summary judgment regarding claims Defendant Nepute allegedly made that Vitamin D is effective for treating and preventing COVID-19.

Also before the Court is Defendant Nepute's Motion for Partial Summary Judgment. Defendant Nepute argues that the Government cannot recover civil penalties under the COVID-19 Act, because it cannot show Defendant Nepute had knowledge of the COVID-19 Act or that his conduct violated the COVID-19 Act. Alternatively, Defendant Nepute argues that at a minimum, he cannot be subject to penalties prior to March 30, 2021.

II. Motion to Exclude Expert Testimony

The Court will first address the Government's Motion to Exclude Expert Testimony. During discovery in this case, Defendant Nepute disclosed three experts: Christina Parks, Ph.D., Michael Holick, M.D., Ph.D., and Defendant Nepute himself. The Government moves to exclude Dr. Parks and Defendant Nepute from testifying as experts entirely. Plaintiff argues they are unqualified to offer opinions in this case. The Government also argues that Dr. Parks's and Defendant Nepute's testimony should be excluded because they failed to adequately articulate a reliable methodology to reach the conclusion that zinc can prevent or treat COVID-19, because they have not adequately explained how, if at all, they weighed conflicting evidence from different

study designs. Finally, the Government argues that Drs. Parks and Holick are unqualified to offer expert opinions as to how consumers would interpret Defendant Nepute's claims, because they lack the specialized expertise to do so.

The parties have submitted an extensive evidentiary record, which includes deposition transcripts, expert reports, curricula vitae, and other exhibits. The Court finds that it can make a proper Daubert determination without the need for an evidentiary hearing or oral argument. Miller v. Baker Implement Co., 439 F.3d 407, 412 (8th Cir. 2006) (district court need not hold a Daubert hearing where parties have opportunity to present argument and evidence before ruling on the motion).

A. Legal Standard

The admission of expert testimony in federal court is governed by Federal Rule of Evidence 702. Lauzon v. Senco Prod., Inc., 270 F.3d 681, 686 (8th Cir. 2001). The proponent of the expert testimony in question, here Defendant Nepute, has the burden to prove its admissibility by a preponderance of the evidence. Id. The district court is "vested with a gatekeeping function, ensuring that 'any and all scientific testimony or evidence admitted is not only relevant, but reliable.'" Union Pac. R.R. v. Progress Rail Servs. Corp., 778 F.3d 704, 709 (8th Cir. 2015) (quoting Daubert, 509 U.S. at 589).

Rule 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Civ. P. 702. The proposed expert testimony must meet three prerequisites in order to be admissible. First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. In other words, the evidence must be relevant. Lauzon, 270 F.3d at 686 (citing 4 Jack B. Weinstein & Margaret A. Berger, Weinstein's Federal Evidence § 702.02[3] (2001)). Second, “the proposed witness must be qualified to assist the finder of fact.” Id. Third, “the proposed evidence must be reliable or trustworthy in an evidentiary sense, so that, if the finder of fact accepts it as true, it provides the assistance the finder of fact requires.” Id. See also Barrett v. Rhodia, Inc., 606 F.3d 975, 980 (8th Cir. 2010); Khoury v. Philips Med. Sys., 614 F.3d 888 (8th Cir. 2010).

B. The Experts

1. Christina Parks, M.D.

Defendants move to exclude Dr. Parks entirely. The Government argues Dr. Parks is unqualified to testify because she lacks the necessary qualifications to offer the opinions in her report. Defendant Nepute responds that Dr. Parks is more than qualified by her education, training, and experience to offer scientific opinions in this case. He asserts Dr. Parks’s background easily qualifies her to identify and analyze the relevant scientific evidence.

According to Defendant Nepute’s expert disclosure report, Dr. Parks will offer testimony of the following:

- [T]he government’s allegations that [Defendant] Nepute claimed that zinc could be used to prevent and/or treat COVID [are] misleading to the point of error.
- [T]here is competent and reliable scientific evidence that zinc is beneficial to the human immune system and prophylactic use with [sic] ‘boost’ immunity.

- [T]here is competent and reliable scientific evidence that zinc helps the immune system [sic] system's anti-viral response.
- [T]here is competent and reliable scientific evidence that zinc can reduce the likelihood of SARS-CoV-2 infection.
- There is competent and reliable scientific evidence that zinc can improve outcomes in COVID-19 patients.

(ECF No. 79, Ex. 3).

Dr. Parks earned a B.S. degree in molecular biology and biochemistry from the University of Wisconsin, Eau Claire, in 1992, and a Ph.D. in cellular and molecular biology from the University of Michigan, Ann Arbor, in 1999. She also earned a teaching certificate from Grand Valley State University. Dr. Parks has not conducted academic or peer-reviewed research since 2000. From 1999-2000, she investigated the molecular mechanisms of adipogenesis. For her doctoral research, from 1993-1999, Dr. Parks worked in a laboratory identifying the signaling molecules that mediate cytokine-induced changes in gene expressions. She personally worked to identify the downstream kinases that were responsible for Elk-1-mediated activation of the genes c-fos, egr-1, and jun B in response to Growth Hormone, and that C/EBP- α is upregulated in fibroblasts differentiating into adipocytes in response to Growth Hormone.

In her academic career, Dr. Parks participated in the writing of six peer-reviewed studies, which were published between 1992 and 2003, and was the primary author of one, which was published in 1998. She has not written a peer-reviewed publication since 2003. (ECF No. 79, Ex. 6 at 5).

None of Dr. Parks's research related to zinc or any dietary supplement. She did not perform research as to whether zinc or any other compound could prevent or treat disease or infection. Dr. Parks's research also did not relate to COVID-19, or severe acute respiratory syndrome

coronavirus 2 (“SARS-CoV-2”), the virus that causes the disease COVID-19. Dr. Parks states in her report that based on her education and research:

I have a deep understanding of immune system signaling and am also able to understand how SARS-CoV-2 induces an immune response leading to a cytokine storm, the role of innate versus adaptive immunity in SARS CoV-2 infection and the mechanism of how SARS CoV-2 infects cells and causes damage, manifesting as COVID-19.

(ECF No. 73, Ex. at 3). She also states, “my years in scientific research enable me to read and interpret scientific literature/studies, including those that I have referenced in my report.” (Id.).

From 2000-2003, Dr. Parks developed and edited science textbooks for secondary schools. Dr. Parks is currently a high school teacher at a homeschool co-op in Michigan. She has taught high school science in a homeschool co-op setting since 2004. Dr. Parks is also the sole proprietor of New Health Paradigms, LLC, which was formed in 2021. She describes this role as providing “[e]ducational presentations and consultations focused on giving the information needed to heal bodily dysfunction at the biochemical and epigenetic level.” (ECF No. 79, Ex. 6 at 1).

The Court finds Dr. Parks’s education and research are insufficient to qualify her to testify as to the clinical benefits of zinc and the prevention and treatment of COVID-19 in this case. Dr. Parks’s academic experience is outdated and not directly relevant to the issues at hand. While her degrees are in cellular and molecular biology, Dr. Parks’s doctorate was awarded 24 years ago. She has not performed any academic research since 2000, and there is no evidence she has engaged in any additional formal continuing education, aside from obtaining a teaching certificate. When Dr. Parks was academically active, she did conduct research on the immune system and HIV, but Dr. Parks has conducted no research on SARS-CoV-2 or on the prevention and treatment of COVID-19. Dr. Parks also has not performed any research into whether zinc could prevent or treat COVID-19 – the core issue for which she is proffered to testify. The Court concurs with the

Government that a doctoral degree from 1999 and research in an adjacent field, which ended in 2000, does not qualify Dr. Parks to testify in 2023 regarding the clinical benefits of zinc and the prevention and treatment of COVID-19. See Shipp v. Murphy, 9 F.4th 694, 701 (8th Cir. 2021) (excluding testimony from a nurse practitioner explaining that the “area of the witness’s competence [must] match the subject matter of the witness’s testimony”) (quotations omitted); Wheeling Pittsburgh Steel Corp. v. Beelman River Terminals, Inc., 254 F.3d 706, 715 (8th Cir. 2001) (finding district court erred in allowing expert with doctoral degree to testify beyond the scope of his expertise, and that the inadmissible opinions expressed by him prejudiced plaintiff in that he offered opinion testimony outside of his area of expertise on ultimate issues of fact that the jury was required to answer); McCabe v. Macaulay, No. 05-CV-73-LRR, 2008 WL 2980009, at *5 (N.D. Iowa Apr. 29, 2008) (holding that an expert’s testimony was “outdated, stale and inadmissible” where he left the relevant field in 1991 and had “not received any formal training or continuing education” since 1989); see also Bone Shirt v. Hazeltine, 461 F.3d 1011, 1026 (8th Cir. 2006) (Gruender, J., concurring) (“Science evolves, and scientific methods that were once considered unassailable truths have been discarded over time. Unreliable testimony based upon those outdated theories and methods must be discarded as well, lest scientific stare decisis ensure that such theories survive only in court.”).

Dr. Parks’s more-recent experience as a science educator also does not qualify her to testify about the clinical benefits of zinc and the prevention and treatment of COVID-19. Dr. Parks’s work as a high school science educator simply does not encompass performing or evaluating original research to determine whether compounds can prevent or treat disease. Furthermore, there is nothing in record to indicate that Dr. Parks’s most recent business venture New Health Paradigms, L.L.C., which was founded in 2021, qualifies her to testify about the clinical benefits

of zinc and the prevent and treatment of COVID-19 in this case. Dr. Parks's curriculum vitae provides the Court with very little insight as to what her new business entails and her role in it. When asked what New Health Paradigms does, Dr. Parks responded as follows: "[I]t's my role as a science educator, taking the very complex deep science and explaining it, at whatever level you want, so – within what I feel is my expertise." (ECF No. 100, Ex. B at 9). This experience does not qualify Dr. Parks to testify in this case as there is nothing to indicate it relates to COVID-19 or zinc. Schmidt v. City of Bella Villa, 557 F.3d 564, 571 (8th Cir. 2009) ("for an expert witness to be qualified based on experience, that experience must bear a close relationship to the expert's opinion").

In response to Plaintiff's motion, Defendant Nepute argues the fact that Dr. Parks is not medical doctor does not disqualify her from testifying as an expert in this case. In support of his argument, Defendant Nepute cites to Obesity Research Institute, LLC v. Fiber Research International, LLC, No. 15-CV-595, 2017 WL 1166307 (S.D. Cal. Mar. 29, 2017). First, while the Court agrees with Defendant Nepute that Dr. Parks need not be a medical doctor to offer expert medical testimony, she must be qualified by her education, training, or experience to testify as to opinions proffered. As discussed above, Dr. Parks's education, training, or experience is insufficient to offer testimony as to the efficacy of zinc in treating and/or preventing COVID-19.

Second, the facts of Obesity Research Institute are readily distinguishable from the case at hand. The court in Obesity Research Institute denied a motion to exclude an expert on the basis that "[f]or the past 30 years" the expert had "analyzed biological molecules, developed and validated assays on the quality of active pharmaceutical ingredients, and compared chemical qualities of drugs;" and "regularly compare[d] drug products in her work." 2017 WL 1166307, at *2 (alterations and internal quotation marks omitted). Thirty years of relevant academic and

practical experience far exceeds Dr. Parks’s qualification. Dr. Parks has a high-level scientific degree and some academic research experience, but her academic career ended more than 20 years. Teaching high school science is not commensurate with developing research or conducting studies concerning the efficacy of zinc and the treatment for COVID-19. See Khoury v. Philips Med. Sys., 614 F.3d 888, 893 (8th Cir. 2010) (district court did not abuse its discretion in finding doctor of ergonomics was unqualified to give expert testimony because he had no training, education, or experience in the design of laboratories or of monitor banks and radiation shields). See also Kennedy v. Baxter Healthcare Corp., 348 F.3d 1073, 1074–75 (8th Cir. 2003) (per curiam) (affirming the district court's exclusion of an expert, who was not a physician or toxicologist, from opining as to “what makes a rubber glove safe or unsafe for allergy purposes or what level of proteins or allergens are necessary to achieve a safe level for allergy purposes”); Weisgram v. Marley Co., 169 F.3d 514, 520 (8th Cir. 1999) (error to allow metallurgist's opinion as to a purported design defect because he had no personal experience and “no metallurgic reason for his conclusion”); Hogland v. Town & Country Grocer of Fredericktown Missouri, Inc., No. 3:14CV00273 JTR, 2015 WL 3843674, at *28–*30 (E.D. Ark. June 22, 2015) (excluding opinion of a “vocational and rehabilitation expert” who was “not a medical doctor” to the extent that opinion was not supported by “medical evidence in the record”).

In sum, the Court finds Dr. Parks lacks the qualifications to testify in this case about the clinical benefits of zinc and the prevention and treatment of COVID-19.

2. Anthony Eric Nepute, D.C.

Plaintiff also moves to exclude Defendant Nepute from testifying as an expert in this case. The Government argues that like Dr. Parks, Defendant Nepute is unqualified to testify because he lacks the necessary qualifications to offer the opinions in his report. Defendant Nepute responds

that he need not be a medical doctor to offer expert medical testimony, and he is more than qualified to testify as an expert based on his education, training, and experience.

Defendant Nepute disclosed that he will offer opinion testimony regarding the following:

- That competent and reliable scientific evidence substantiates his statements regarding vitamin D and zinc with respect to viral respiratory infections generally, and Covid-19 particularly, including that they:
 - Help strengthen or boost the immune system;
 - Can reduce the risk of infection with Covid-19; and
 - Can improve outcomes for Covid-19 patients.
- That statements he made were not false or misleading but were supported by ample competent and reliable scientific evidence.
- That he is under an obligation under the Hippocratic Oath to recommend Vitamin D and zinc supplementation based on long-standing consensus among the scientific community regarding the known benefits of Vitamin D and zinc, and the absence of negative side effects for Vitamin D and the minimal side effects for zinc.

(ECF No. 79, Ex. 5). Defendant Nepute states that “Out of an abundance of caution, [he] provided a ‘hybrid’ disclosure pursuant to Rule 26(a)(2)(C) to forestall any argument by Plaintiff that it was prejudiced by a failure to disclose Defendant Nepute’s opinions and expertise.” (ECF No. 100 at 7).

Defendant Nepute earned a B.S. degree from Millikin University in Sports Medicine and Athletic Training. Defendant Nepute was awarded a Doctor of Chiropractic degree in 2006 from Logan University. During his residency, Defendant Nepute performed a wide variety of work in a clinical setting. Defendant Nepute has had some post-doctorate training, which includes obtaining certification as a Doctor of Natural Medicine, a diplomat program in internal health, and he is credentialed as a Certified Nutrition Specialist.

Defendant Nepute has conducted no studies or research. He has not led or participated in any clinical trials. He has not published any academic papers in any peer-reviewed journal.

Defendant Nepute owns Nepute Wellness Center where he sees patients, but Defendant Nepute does not practice medicine. (ECF No. 79, Ex. 7 at 49, 98). He is not a medical doctor. He does not write prescriptions for his patients because under applicable state law, he is not permitted to do so as a chiropractor. The primary focus of Defendant Nepute's practice is the treatment of neuromusculoskeletal complaints and fatigue. He also provides "nutritional care." (ECF No. 79, Ex. 7 at 65). Defendant Nepute does not treat disease in his chiropractic practice, and there is no evidence in the record that he has any experience treating infectious diseases, and more specifically, COVID-19. (ECF No. 79, Ex. 7 at 66). Defendant Nepute's practice does not require him to conduct assessments of the clinical efficacy of compounds to prevent or treat disease.

Rule 702 requires that "the area of the witness's competence matches the subject matter of the witness's testimony." Robinson v. Geico Gen. Ins. Co., 447 F.3d 1096, 1100 (8th Cir. 2006). The Court finds Wheeling Pittsburgh Steel Corporation v. Beelman River Terminals, Inc., 254 F.3d 706 (8th Cir. 2001) instructive as to the issue. There, the defendant proffered the testimony of an "eminently qualified" hydrologist to testify about flooding in a warehouse. Id. 715. The Eighth Circuit found it was reversible error for the district court to have allowed the hydrologist to testify at trial. In its analysis, the Eighth Circuit noted the following:

[The doctor in hydrology] sorely lacked the education, employment, or other practical personal experiences to testify as an expert specifically regarding safe warehousing practices. [The doctor in hydrology] did not study warehousing practices during his formal education, he has not written about warehousing practices in any of his sixty-plus published articles, and he has never been employed by a warehouseman during any of the twenty-one projects on which he has worked. Although he has worked with entire communities and shopping centers, he has never prepared emergency response plans specifically for storage facilities or warehouses.

Id.

Like the expert in Wheeling Pittsburgh Steel, Defendant Nepute is a qualified expert. He is a chiropractor and is an expert in chiropractic care and running a chiropractic practice. He is not an expert in epidemiology, infectious diseases, virology, or immunology. Defendant Nepute lacks the education, training, and experience to testify regarding the clinical benefits of Vitamin D and zinc to prevent or treat COVID-19. See Kennedy, 348 F.3d at 1074–75; Weisgram, 169 F.3d at 520. See also In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig., 524 F. Supp. 2d 1166, 1176 (N.D. Cal. 2007) (medical professional unqualified to offer general causation testimony because he lacked “specialized epidemiology training”, had only published on topics unrelated to subject matter of the lawsuit, and had “never participated in an observational study of any kind”). Defendant Nepute provides the Court with no cases in which a court allowed a chiropractor to testify regarding treatment for diseases, and the Court has found none. The fact that Defendant Nepute declares himself an expert in supplements and the treatment and prevention of COVID-19 does not make it so. Guilfoyle v. Beutner, No. 2:21-CV-5009, 2021 WL 4594780, at *11 (C.D. Cal. Sept. 14, 2021) (excluding physician, who was “self-declared” expert in epidemiology and “evidence-based medicine”). The Court finds Defendant Nepute is not qualified to testify as an expert in this case.

The fact that the Court finds Defendant Nepute is not a qualified expert in this case does not preclude him from testifying about the scientific basis upon which he made the alleged misstatements. The Government does not dispute that, as a fact witness, Defendant Nepute can supply what he claims is “the scientific basis upon which he made the alleged misstatements.” (EFC No. 100 at 6). Such testimony would go to whether Defendant Nepute had sufficient “substantiation for [his] representation[s] prior to making [them] in an advertisement.” FTC v. Direct Mktg. Concepts, Inc., 569 F. Supp. 2d 285, 298 (D. Mass. 2008), aff’d, 624 F.3d 1 (1st Cir.

2010). But Defendant Nepute may not testify as an expert on whether such evidence is sufficient to satisfy the relevant scientific community that Vitamin D and zinc can treat and/or prevent COVID-19.

3. Michael Holick, M.D., Ph.D.

Finally, the Government moves to exclude Dr. Holick from testifying as to how a consumer would interpret particular statements made by Defendant Nepute. The Government argues Dr. Holick, who is a medical doctor and has a doctoral degree in biochemistry, does not have the expertise to testify regarding the interpretation of marketing claims.

In his expert report, Dr. Holick noted the following:

I note that [Plaintiff's expert] was asked to assume that the Defendants made certain statements that formed the basis for his report and opinions. However, in his deposition Dr. Dubberke was unable to identify any actual statement. I attempted, but was unable to correlate the Defendants' statements in the record I reviewed with the government's characterization of those statements. It seems that Dr. Dubberke was answering hypothetical characterizations of statements posed by the government rather than actual statements made by the Defendants.

(ECF No. 79, Ex. at 20). The Government points to this section in Dr. Holick's report in support of its contention that he is offering testimony as how a consumer would interpret Defendant Nepute's statements.

Defendant Nepute states in his response that Dr. Holick will not opine "as to what a reasonable consumer would have understood from any of Defendant [Nepute's] statement[s], nor the net impression to consumers of any particular statement. At most, [he] will simply state that [he has] not seen the alleged misstatements in the record." (ECF No. 100 at 16).

As discussed below, it is for the jury to determine whether Defendant Nepute made misleading statements conveying the "net impression" that Vitamin D or Zinc can prevent or treat COVID-19, or that Vitamin D and Zinc are more effective than available vaccines. To the extent

Dr. Holick intends to offer testimony that Defendant Nepute did not make misleading representations in his publications, the Court grants Plaintiff's motion to exclude the testimony. Dr. Holick is a medical expert, not an expert in marketing. Whether Defendant Nepute made misleading statements is an ultimate issue of fact for the jury to decide, and Dr. Holick is not qualified to offer opinions as to whether marketing statements Defendant Nepute made are likely to mislead a reasonable consumer. Fed. R. Evid. 702; Lauzon, 270 F.3d at 686 (8th Cir. 2001).

The Court now turns the parties' cross motions for partial summary judgment.

III. Motions for Partial Summary Judgment

A. Legal Standard

The Court may grant a motion for summary judgment if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986); Torgerson v. City of Rochester, 643 F.3d 1031, 1042 (8th Cir. 2011) (en banc). The substantive law determines which facts are critical and which are irrelevant. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). Only disputes over facts that might affect the outcome will properly preclude summary judgment. Id. Summary judgment is not proper if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. Id.

A moving party always bears the burden of informing the Court of the basis of its motion. Celotex Corp., 477 U.S. at 323. Once the moving party discharges this burden, the nonmoving party must set forth specific facts demonstrating there is a dispute as to a genuine issue of material fact, not the "mere existence of some alleged factual dispute." Fed. R. Civ. P. 56(e); Anderson, 477 U.S. at 248. "The nonmoving party may not rely on allegations or denials," but rather "must

substantiate [its] allegations with sufficient probative evidence that would permit a finding in [its] favor on more than mere speculation or conjecture.” Carter v. Pulaski Cnty. Special Sch. Dist., 956 F.3d 1055, 1059 (8th Cir. 2020) (quoting Ball v. City of Lincoln, Neb., 870 F.3d 722, 727 (8th Cir. 2017) (cleaned up)). “Small factual disputes about the underlying events . . . could only create the ‘metaphysical’ kind of doubt that the Supreme Court decried in Matsushita Electric Industrial Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986).” Main v. Ozark Health, Inc., 959 F.3d 319, 327 (8th Cir. 2020) (cleaned up; quoted case omitted).

In passing on a motion for summary judgment, the Court must view the facts in the light most favorable to the nonmoving party, and all justifiable inferences are to be drawn in his favor. Celotex Corp., 477 U.S. at 331. The Court’s function is not to weigh the evidence but to determine whether there is a genuine issue for trial. Anderson, 477 U.S. at 249. “‘Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge.’” Torgerson, 643 F.3d at 1042 (quoting Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 150 (2000)).

B. The Government’s Motion for Partial Summary Judgment

The Government moves for summary judgment as to liability under the FTC Act and Covid-19 Act. Plaintiff asks the Court to find Defendant Nepute liable for 12,859,355 violations of the FTC Act and 10,175,234 violations of the COVID-19 Act.

The FTC Act provides the Government with enforcement authority regarding false advertising. The COVID-19 Act prohibits deceptive advertising associated with the treatment, cure, or prevention of COVID-19. Section 5 of the FTC Act provides that “unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.” 15 U.S.C. § 45(a)(1). Section 12 of the FTC Act

provides that “it shall be unlawful for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement – (1) By United States mails, or in or having an effect upon commerce, by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of food, drugs, devices, services, or cosmetics; or (2) By any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in or having an effect upon commerce, of food, drugs, devices, services, or cosmetics.” 15 U.S.C. § 52(a). A “false advertisement means an advertisement, other than labeling, which is misleading in a material respect.”³ 15 U.S.C. § 55(a)(1).

To prevail on a claim of false advertising under the FTC Act, the Government must show the following:

- (1) there is a representation, omission, or practice that
- (2) is likely to mislead consumers acting reasonably under the circumstances, and
- (3) the representation, omission, or practice was material.

F.T.C. v. Quincy Bioscience Holding Co., Inc., 753 F. App’x 87, 89 (2d Cir. 2019); F.T.C. v. E.M.A. Nationwide, Inc., 767 F.3d 611, 630 (6th Cir. 2014); F.T.C. v. Stefanchik, 559 F.3d 924, 928 (9th Cir. 2009); F.T.C. v. Peoples Credit First, LLC, 244 F. App’x 942, 944 (11th Cir. 2007).

As to the first element of the false advertising standard under the FTC Act, the representation may be explicitly stated in the advertisement. F.T.C. v. Direct Mktg. Concepts, Inc., 569 F. Supp. 2d 285, 298 (D. Mass. 2008), aff’d, 624 F.3d 1 (1st Cir. 2010). In the absence of an explicit statement, a court may determine whether the advertisement in question makes a

³ Under the FTC Act, the dissemination of false advertisements under Section 12 is a deceptive act or practice in violation of Section 5. 15 U.S.C. § 52(b). Therefore, Sections 12 and 5 are often “applied in tandem as the basis for an FTC action against an alleged false advertiser.” F.T.C. v. Direct Mktg. Concepts, Inc., 624 F.3d 1, 7–8 (1st Cir. 2010).

representation by considering whether, from the point of view of a reasonable consumer-viewer, the net impression of the advertisement is to make such a representation. Id. (citations omitted).

The COVID-19 Act made it unlawful during the COVID-19 public health emergency for any person, partnership, or corporation to engage in a deceptive act or practice in or affecting commerce in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a) “associated with the treatment, cure, prevention, mitigation, or diagnosis of COVID-19.” Pub. L. No. 116-260, Title XIV, § 1401(b)(1). In a prior Memorandum and Order, this Court ruled that the Government may seek civil penalties pursuant to 15 U.S.C. § 45(m)(1)(A) for violations of the COVID-19 Act. (ECF No. 47).

In its Motion for Partial Summary Judgment, the Government seeks a number of rulings from the Court. The Government moves that the Court find as a matter of law that Defendant Nepute’s publications – his Facebook videos, Wellness Warrior emails, and radio shows – are “advertisements” within the meaning of FTC Act. The Government also moves that the Court find as a matter of law that the advertisements were unsubstantiated and misleading, that Defendant Nepute can be held liable for Quickwork advertisements, and that he disseminated over ten million false advertisements.

1. Are Defendant Nepute’s publications advertisements?

In general, advertisements provide consumers with information regarding products or services for sale in commerce. The FTC is charged with eliminating unfair and deceptive business practices, and in an attempt to protect consumers, Congress delegated to the FTC the authority to regulate false or misleading advertising. Under Section 12 of the FTC Act, an “advertisement” is a publication that has the “tendency or capability to induce the sale of [a] product.” Nat’l Comm’n on Egg Nutrition v. F.T.C., 570 F.2d 157, 163 (7th Cir. 1977); see 15 U.S.C. § 52(a) (describing

an “advertisement” as that “which is likely to induce, directly or indirectly the purchase” of a good). Publications “designed to convey the point that consumption of a particular product [will convey a health benefit] are clearly likely to induce the purchase of that product.” Nat’l Comm’n on Egg Nutrition, 570 F.2d at 163. The Government argues it is clear in this case that Defendant Nepute’s publications are advertisements subject to enforcement actions under the FTC Act and the COVID-19 Act.

In general, the parties do not dispute the facts of this case. It is undisputed that Defendant Nepute used several platforms to share the purported benefits of Vitamin D and zinc and his Wellness Warrior supplements. The parties do not dispute that Defendant Nepute posted videos on Facebook, that emails were sent to Quickwork subscribers, or that Defendant Nepute hosted radio shows that aired on FM radio and were later available to stream online.⁴ Alongside claims about the benefits of Vitamin D and zinc, it is undisputed that consumers were provided with websites where they could obtain a “free” bottle of Wellness Warrior Vitamin D and zinc and purchase additional bottles. There are 64 publications at issue on the Government’s Motion for Partial Summary Judgment – 16 Facebook videos, 33 emails, and 15 radio shows. Plaintiff argues the undisputed evidence establishes all of these publications are advertisements.

Defendant Nepute responds that his publications are not advertisements, but rather they are educational materials protected by the First Amendment. He argues the fact “that certain portions of the [publications] directed listeners back to Quickwork’s website[s] is not irrefutable evidence that the [c]ontent was commercial in nature.” (ECF No. 112 at 17). He points to the fact that “in many cases, listeners were directed to the Quickwork website[s] for the express purpose of

⁴The parties also do not dispute the accuracy of the transcripts and emails the Government submitted in support of its Motion for Partial Summary Judgment.

providing further health information.” (Id.). He argues that because the Quickwork’s websites do more than simply sell vitamins and supplements – they are “interconnected with the exposition of ideas about how to live a healthy life” – references to the Quickwork websites in the publications do not make them advertisements. (Id.). Defendant further argues that the content of his publications is infused with political speech related to the governmental response to the COVID-19 pandemic. He argues this speech is entitled to the highest level of constitutional protection under the First Amendment.

As an initial matter, Defendant Nepute did not assert a First Amendment defense in his Answer and, therefore, is precluded from raising this factually undeveloped defense at this stage in the proceedings. See Fed. R. Civ. P. 8(c); Arnold v. Treadwell, 642 F. Supp. 2d 723, 729 (E.D. Mich. 2009) (holding the First Amendment was an affirmative defense that should have been pleaded as such in the answer so that facts could be developed on what level of protection applied). Even if the Court were to consider the defense, Defendant Nepute’s speech is not entitled to protection under the First Amendment. First, for the reasons discussed below, the Court finds Defendant Nepute’s publications were advertisements and, therefore, are commercial speech. Second, the Court finds there are issues of fact as to whether they were misleading and/or false, and there is no First Amendment protection for misleading advertisements.

The Supreme Court has afforded varying degrees of First Amendment protection to different categories of speech. Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60, 64 (1983). Commercial speech is afforded less protection than other forms of expression. Id. The fact that Defendant Nepute contends his speech was educational or in the public’s interest is not determinative to whether the speech is commercial speech. Nat’l Comm’n on Egg Nutrition, 570 F.2d at 163. Speech can be categorized as commercial speech, “notwithstanding the fact that [it]

contain discussions of important public issues.” Bolger, 463 U.S. at 68. See also Porous Media Corp. v. Pall Corp., 173 F.3d 1109, 1121 (8th Cir. 1999) (explaining “‘commercial speech’ need not originate solely from economic motives” and that a defendant’s speech was commercial in nature despite his purported “nobler concerns”). “Advertisers should not be permitted to immunize false or misleading product information from government regulation simply by including references to public issues.” Id. The Supreme Court has made clear that “advertising which ‘links a product to a current public debate’ is not thereby entitled to the constitutional protection afforded noncommercial speech.” Id. (quoting Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of New York, 447 U.S. 557, 563 (1980)). Furthermore, for commercial speech to come within the First Amendment, “it at least must concern lawful activity and not be misleading.” Cent. Hudson Gas & Elec. Corp., 447 U.S. at 566. See also POM Wonderful, LLC v. F.T.C., 777 F.3d 478, 499 (D.C. Cir. 2015) (declining to find deceptive commercial speech to be protected by the First Amendment). In other words, the First Amendment does not protect false, misleading, or deceptive advertisements. Id.

When deciding whether speech is commercial, courts generally consider: “(i) whether the communication is an advertisement, (ii) whether it refers to a specific product or service, and (iii) whether the speaker has an economic motivation for the speech.” Porous Media Corp., 173 F.3d at 1121 (citing Bolger, 463 U.S. at 66–67). The Court now turns to whether Defendant Nepute’s publications were advertisements. It is undisputed that since at least July 2020, Nepute has created numerous lengthy monologue videos promoting Vitamin D and zinc supplements, which he has posted on Facebook pages and websites. It is also undisputed that all of the videos direct viewers to at least one of Quickwork’s various websites, including “freevitamindeals.com,” “freevitamindeal.com,” “myfreezinc.com,” and “ericnepute.com,” where consumers can purchase

and subscribe to Wellness Warrior products. It is further undisputed that since at least September 2020, Quickwork's team has sent emails to hundreds of thousands of Wellness Warrior subscribers from the info@wellnesswarrior.club account, with the sender identified as "Dr. Eric Nepute." Quickwork's team used Nepute's videos to create these emails and included excerpts from the videos about the purported benefits of Vitamin D and zinc. Often, these emails referred subscribers to Nepute's videos. The emails also frequently included consumer testimonials extolling the purported health benefits of Vitamin D and zinc for COVID-19 treatment and prevention.

The Court has reviewed the video transcripts and emails and finds the evidence does not support Defendant Nepute's contention that viewers or readers were referred to the websites for educational purposes. For example, in a video dated January 17, 2021, Defendant Nepute stated the following:

So here's what I want you to do. Go to freevitamindeals.com – that's freevitamindeals.com so that you can get the products that you need. I'm giving you a bottle of zinc for free, a bottle of D3 for free. I need you to buy that immune pack. You'd be silly not to get it. If you don't want to, that's fine. But I'm just telling you what you need to do. According to the research, it's what you should be doing.

(ECF No. 113 at 44). In each of his videos, Defendant Nepute delivered the message that the consumption of Vitamin D and/or zinc will provide certain health benefits. This message was also delivered in the emails. By the delivering this message in conjunction with providing the websites where viewers and readers could purchase Vitamin D and zinc, the videos and emails were clearly likely to induce the purchase of these products. Nat'l Comm'n on Egg Nutrition, 570 F.2d at 163. In addition, the videos instructed, either explicitly or by clear implication, that viewers "needed" to purchase Defendant Nepute's vitamins and/or supplements. Therefore, the Court finds the undisputed evidence establishes that the videos and emails at issue on summary judgment are commercial speech and are advertisements within the meaning of the FTC Act.

Whether Defendant Nepute's radio shows are advertisements is a closer call. In September 2021, Defendant Nepute began hosting a radio show called "Real Talk with Dr. Eric Nepute" on the Missouri-based Real Talk Radio Network, which airs on KRTK 93.3 FM and affiliated radio stations. The shows, which were two hours in length, could be watched live on Real Talk's Facebook page, and the second hour was available for streaming on www.brighteonradio.com. Real Talk also made audio or video recordings available for some broadcasts on its website, its CloutHub page, and its Facebook page. Defendant Nepute used the radio shows to discuss the purported benefits of Vitamin D and zinc. The shows, however, were not limited to discussing Vitamin D and zinc, or even COVID-19, vaccines, or other available treatments. In his shows, Defendant Nepute discussed a wide variety of political topics and current events. During commercial breaks, the show aired what Defendant Nepute characterizes as "generic Wellness Warrior commercials," which were recorded by Defendant Nepute. (ECF No. 112). Defendant Nepute contends these commercials are separate and apart from the content of the radio shows. The Government urges the Court to find that material outside the scheduled commercial breaks in the radio show were advertisements – in other words, that the radio shows themselves were advertisements for Wellness Warrior products.

The Court has reviewed transcripts of the radio shows and, viewing them in a light most favorable to Defendant Nepute, finds Defendant Nepute's characterization of the evidence is not supported by the record. The Court agrees with Defendant Nepute that during the radio shows he discussed a number of topics concerning politics and current events, and the entire radio shows do not constitute advertisements. The Court also agrees with Defendant Nepute that there were advertisements for Wellness Warrior products aired during the commercial breaks, and these advertisements were more general in nature. However, the Court finds the advertisements were

not limited to the commercial breaks. During the radio programs themselves – outside the scheduled commercial breaks – Defendant Nepute made statements that the consumption of Vitamin D and/or zinc will provide certain health benefits; he delivered his message in conjunction with providing websites where listeners could purchase Wellness Warrior Vitamin D and zinc supplements; and he instructed, either explicitly or by clear implication, that listeners should purchase vitamins and/or supplements. Therefore, the Court finds that some segments of the radio shows at issue on summary judgment – not merely the commercials aired during commercial breaks – were clearly likely to induce the purchase of products and are advertisements within the meaning of the FTC Act. Nat’l Comm’n on Egg Nutrition, 570 F.2d at 163.

2. Were the advertisements misleading, false, or unsubstantiated?

Under the FTC Act, a defendant is liable for deceptive advertising for any (1) “representation, omission, or practice” (2) that “is likely to mislead consumers acting reasonably under the circumstances,” and (3) “is material.” F.T.C. v. Pantron I Corp., 33 F.3d 1088, 1095 (9th Cir. 1994) (citation omitted); F.T.C. v. Am. Screening, LLC, No. 4:20-CV-1021 RLW, 2022 WL 2752750, at *7 (E.D. Mo. July 14, 2022).

“When assessing the meaning and representations conveyed by an advertisement, the court must look to the advertisement’s overall, net impression rather than the literal truth or falsity of the words in the advertisement.” F.T.C. v. Nat’l Urological Grp., Inc., 645 F. Supp. 2d 1167, 1189 (N.D. Ga. 2008), aff’d, 356 F. App’x 358 (11th Cir. 2009). If an advertisement “(1) expressly states or (2) clearly and conspicuously implies a claim, ‘the court need not look to extrinsic evidence to ascertain whether the advertisement made the claim.’” F.T.C. v. Fleetcor Techs., Inc., 620 F. Supp. 3d 1268, 1289 (N.D. Ga. 2022) (citation omitted). Where an advertisement is amenable to more than one interpretation, it is deceptive if “at least a significant minority of

reasonable consumers” would “likely” interpret the advertisement as making the misleading claim. POM Wonderful, LLC, 777 F.3d at 490 (citation omitted).

To establish that a representation is likely to mislead, the Government may proceed under a “falsity theory,” a “reasonable basis theory,” or both. Pantron I, 33 F.3d at 1096. Under a falsity theory, an “advertisement may be false by either misstating a fact or failing to disclose a material fact.” F.T.C. v. Pharmtech Rsch., Inc., 576 F. Supp. 294, 300 (D.D.C. 1983); see 15 U.S.C. § 55(a) (explaining an advertisement is “false” if it “fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity”). Under a reasonable basis theory, the Government must show that an advertiser lacked sufficient “substantiation for the representation prior to making it in an advertisement.” Direct Mktg. Concepts, Inc., 569 F. Supp. 2d at 298; accord F.T.C. v. Johnson, 96 F. Supp. 3d 1110, 1150 (D. Nev. 2015). Under either theory, the Government need not “prove that customers were actually deceived,” or the advertiser “intended to deceive customers.” Fleetcor, 620 F. Supp. 3d at 1289.

A representation or omission is “material if it involves information likely to affect a customer’s decision to purchase a particular product or service.” Am. Screening, 2022 WL 2752750, at *7 (citation omitted). “Express or clearly implied representations used to induce the purchase of a particular product or service are presumptively material.” Fleetcor, 620 F. Supp. 3d at 1290 (citation omitted). So are claims that “significantly involve health, safety, or other issues that would concern reasonable consumers.” F.T.C. v. QT, Inc., 448 F. Supp. 2d 908, 960 (N.D. Ill. 2006) (citation omitted), amended on reconsideration in part, 472 F. Supp. 2d 990 (N.D. Ill. 2007), aff’d, 512 F.3d 858 (7th Cir. 2008), and aff’d, 512 F.3d 858 (7th Cir. 2008); Nat’l Urological Grp., 645 F. Supp. 2d at 1190.

The Government argues in its Motion for Partial Summary Judgment that on “countless occasions” Defendant Nepute made express and implied claims that Vitamin D and zinc provide equal or better protection against COVID-19 than the vaccines, and that zinc is effective for preventing and treating COVID-19. (ECF No. 96 at 14). Plaintiff further asserts that Defendant Nepute has not proffered any evidence showing that Vitamin D or zinc provide equal or better protection than the vaccines or that zinc is effective for preventing and treating COVID-19, and there is no genuine dispute that Defendant Nepute lacks any reasonable basis to support these claims. Finally, the Government contends these claims were material and likely affected consumers’ decisions to purchase the Wellness Warrior products.

a. *Was there a reasonable basis for the disputed claims*

The Court will first address whether Defendant Nepute had a reasonable basis for the disputed claims. As to whether there is sufficient evidence to substantiate a claim that Vitamin D and/or zinc provide equal or better protection against COVID-19 than the vaccines, Defendant Nepute has no admissible expert testimony that would support such a claim. See POM Wonderful, LLC, 777 F.3d at 490 (finding there must be competent and reliable scientific evidence, that would satisfy the relevant scientific community, that the defendants’ claims are true); Junk v. Terminix Int’l Co., 628 F.3d 439, 450 (8th Cir. 2010) (explaining “expert medical and toxicological testimony is unquestionably required” to show that exposure caused health outcome) (quotation omitted); In re Baycol Prod. Litig., 596 F.3d 884, 889 (8th Cir. 2010) (requiring plaintiff to prove “medical causation through the use of a medical expert” in suit alleging that drug caused adverse health outcome).

Defendant Nepute argues that he need not present such evidence, because he has never made a claim that that Vitamin D and/or zinc provide equal or better protection against COVID-

19 than the vaccines. Defendant Nepute states that in the advertisements at issue in this case, he discussed the vaccine's side effects and lack of efficacy, but these statements were not comparisons to the efficacy of Vitamin D and zinc, and he has adequate evidence to support the claims he did make.⁵ The Government, however, is not challenging claims Defendant Nepute made about the vaccines in general, but rather it is challenging claims Defendant Nepute made that Vitamin D and zinc are better than available vaccines. The Court finds the Government is entitled to summary judgment on the issue that there is no substantiation for representing that Vitamin D and/or zinc provide equal or better protection against COVID-19 than the vaccines, to the extent Defendant Nepute made such a claim in his advertisements.

The Court now turns to whether there is substantiation for a claim that zinc is effective for preventing and treating COVID-19. Defendant Nepute argues that his and Dr. Parks's testimony are more than sufficient to create a question of fact as to the substantiation of the claims regarding zinc. As addressed above, however, the Court finds that Dr. Parks and Defendant Nepute are unqualified to testify as experts in this case. There is a complete lack of evidence in the record to substantiate a claim that zinc is effective for preventing and treating COVID-19, and no reasonable jury could find that Defendant Nepute had a reasonable basis to support any such claim. The Court finds the Government is entitled to summary judgment on this issue.

⁵Defendant Nepute maintains that his position on COVID-19 vaccines has also been consistent – that individuals should get a vaccine if they wish, but should have informed consent when doing so and, like any medical procedure, should discuss the decision with their doctor. He also asserts that he has not suggested that vitamin supplementation and the COVID-19 vaccines are mutually exclusive alternatives, but rather that vitamin supplementation can be pursued regardless of an individual's decision to vaccinate. Defendant Nepute may have made these assertions in his advertisements, but they are irrelevant to the Government's charges that Defendant Nepute made false and misleading claims in advertising that Vitamin D and/or zinc are more effective at preventing COVID-19 than available vaccines.

b. Were the disputed claims material?

In order for a defendant to be liable for false advertisement under the FTC Act, the misrepresentation must be material. “A representation or omission is material if it is the kind usually relied on by a reasonably prudent person.” Nat’l Urological Grp., Inc., 645 F. Supp. at 1190 (quotation and citations omitted). “A claim is considered material if it involves information that is important to consumers and, hence, likely to affect their choice of, or conduct regarding, a product.” QT, Inc., 448 F. Supp. 2d at 960. “Express claims, or deliberately made implied claims, used to induce the purchase of a particular product or service are presumptively material.” F.T.C. v. Windward Mktg., Inc., Case No. 1:96-cv-615F, 1997 WL 33642380, at *10 (N.D. Ga. Sept. 30, 1997). Additionally, “claims that significantly involve health, safety, or other issues that would concern reasonable customers’ [are] presumptively material.” Nat’l Urological Grp., Inc., 645 F. Supp. 2d at 1190 (quoting QT, Inc., 448 F. Supp. 2d at 956–66).

There appears to be no dispute that claims that Vitamin D and/or zinc provide equal or better protection against COVID-19 than the vaccines, or that zinc is effective for treating and/or preventing COVID-19, would be material in advertising the Wellness Warrior supplements. This would be especially true during the COVID-19 pandemic. The Government is entitled to summary judgment on this issue.

c. Is there undisputed evidence that the advertisements contain the disputed claims?

Next the Court turns to whether the advertisements at issue on summary judgment made claims that: (1) Vitamin D and/or zinc provide equal or better protection against COVID-19 than available vaccines; or (2) zinc is effective for treating and/or preventing COVID-19.

In support of its Motion for Partial Summary Judgment, the Government points to 8 videos, 20 emails, and 11 radio shows in which it claims Defendant Nepute made unlawful representations

in advertisements that Vitamin D and/or zinc provide equal or better protection against COVID-19 than available vaccines. In support of its claims that Defendant Nepute made unlawful representations in advertisements that zinc is effective for preventing and/or treating COVID-19, the Government points to 8 videos, 13 emails, and 4 radio shows. In its Statement of Uncontroverted Material Facts (“SUMF”), which is approximately 200 pages, Plaintiff provides the Court with selections from the advertisements. It attached to the SUMF, as supporting exhibits, transcripts from the videos and radio shows, as well as copies of the emails, which total more than a thousand pages. The Government argues that in these advertisements across multiple platforms, the message Defendant Nepute conveyed was consistent with the representative samples highlighted in the SUMF. Therefore, the Government argues, the undisputed evidence establishes that the overall, net impression of each of the advertisements was either that (1) Vitamin D and/or zinc provide equal or better protection against COVID-19 than available vaccines; or (2) zinc is effective for treating and/or preventing COVID-19, both of which are unsubstantiated.

The Court has carefully examined the voluminous record in this case, including the emails and transcripts of videos and radio shows. The Court disagrees with the Government’s contention that Defendant Nepute’s message was the same throughout his advertisements. The videos and radio shows appear to have been unscripted, impromptu performances, which at times were rambling and disorganized. Certainly, Defendant Nepute made assertions about Vitamin D, zinc, COVID-19, and the vaccines, among other things, in his advertisements, but he often jumped from topic to topic and did not make connections between his statements. Furthermore, some of the representations he made about Vitamin D and zinc were vague or ambiguous. Drawing inferences most favorable to Defendant Nepute, the Court finds the issue of whether representations made in each of the 64 advertisements created the net impression that either (1) Vitamin D and/or zinc

provide equal or better protection against COVID-19, or (2) that zinc is effective for preventing and/or treating COVID-19, is a matter for the Government's presentation of evidence at trial and determination by the jury. United States v. J. B. Williams Co., 498 F.2d 414, 433 (2d Cir. 1974) (examining on summary judgment whether claims about Geritol were necessarily deceptive and finding while the FTC's proposed "inference [as to what the advertisement was conveying] may be conceivable, it certainly is not one that a jury would be compelled to draw."). The Court denies the Government's motion for summary judgment as to this issue.

3. Defendant Nepute's individual liability.

In its motion, the Government argues Defendant Nepute is liable for deceptive advertisements made by Quickwork. Defendant Nepute does not dispute that he is responsible for the videos and radio shows he made but argues he cannot be held liable for allegedly deceptive emails Quickwork sent to Wellness Warrior subscribers. Defendant Nepute argues he cannot be individually liable for Quickwork's emails because he neither "participated directly in the making of the emails [n]or had authority to control them." (ECF No. 112 at 27).

An individual is liable for a company's violations of the FTC Act if he (1) "either participated directly in the deceptive acts or practices or had the authority to control them"; and (2) "either knew or should have known about the deceptive practices." F.T.C. v. Bay Area Bus. Council, Inc., 423 F.3d 627, 636 (7th Cir. 2005) (emphasis added). Knowledge is proven "with evidence that the individuals had 'actual knowledge of the material misrepresentations, reckless indifference to the truth or falsity of such misrepresentations, or an awareness of high probability of fraud along with an intentional avoidance of the truth.'" Id. (citation omitted); Stefanchik, 559 F.3d at 924.

The undisputed evidence establishes Defendant Nepute participated directly in creating the Quickwork emails that were sent to subscribers and/or had the authority to control them. Defendant Nepute is one of three members of Quickwork, a limited liability company, and he admitted that he was authorized to carry out any and all of the objects and purposes of the company. It is undisputed that Defendant Nepute was responsible for ensuring Quickwork's product claims were accurate. Defendant Nepute personally made all the videos at issue, and emails sent to Quickwork subscribers were based on Defendant Nepute's videos and statements. Quickwork's Chief Marketing Officer testified that "99.9 percent of every e-mail was directly taken from [Nepute's] videos." (ECF No. 96-6 at 132:16-23). Furthermore, all of the emails were sent by "Dr. Eric Nepute." (ECF No. 98-22 at 2). Considering Defendant Nepute's plenary authority "to control the marketing activity and representations about his product[s]," and the fact that he created the content used in the emails, no reasonable factfinder would conclude he did not have the ability to control Quickwork's email advertisements. Stefanchik, 559 F.3d at 931. See also F.T.C. v. Grant Connect, LLC, 763 F.3d 1094, 1103 (9th Cir. 2014) (holding a defendant liable under the FTC Act where he "participated in designing and approving" misleading content even though that content was ultimately sent while he was imprisoned).

As for what Defendant Nepute knew about the emails, Defendant Nepute argues he cannot be held liable because "[t]he emails were not sent to [him] for approval prior to them being sent," and "he was not even aware when the emails were sent or to whom they were sent." (ECF No. 112 at 28). But Defendant Nepute need not have detailed knowledge of each step of the publication. See F.T.C. v. LeadClick Media, LLC, 838 F.3d 158, 169 (2d Cir. 2016) (explaining that a defendant can be liable even where they are "not solely responsible for a deceptive scheme" and reasoning that the "creation and distribution of most any good is subject to a host of sequential

steps”). Defendant Nepute was an owner and manager of Quickwork, he created the content that was being used in its emails, and he knew the emails were being sent out. Considering the extent of his control and responsibilities, the undisputed evidence establishes Defendant Nepute knew or should have known about the emails and their contents. The Court finds Defendant Nepute can be held individually liable for Quickwork’s advertising, and the Government is entitled to summary judgment as to this issue. American Screening, LLC, 2022 WL 2752750, at *9; Stefanchik, 559 F.3d at 931.

4. Disseminations.

In its Motion for Partial Summary Judgment as to liability, the Government asks the Court to find Defendant Nepute liable for 10,175,234 violations of the COVID-19 Act. According to the Government, each dissemination of a deceptive advertisement is a separate violation under the FTC and COVID-19 Acts. See 15 U.S.C. § 52(a) (“It shall be unlawful . . . to disseminate, or cause to be disseminated, any false advertisement”). The Government calculates that the 16 Facebook videos, 33 emails, and 15 radio shows have been disseminated 10,175,234 times for purposes of the COVID-19 Act, but does not explain how it reaches this number of claimed disseminations. It appears the Government added the number of “views” for the videos on Facebook, the number of email addresses to which the email advertisements were sent, and the number of “views” the radio shows had after they were posted on Facebook and CloutHub to reach its calculation.

The Court has not determined that Defendant Nepute violated the COVID-19 Act, and there appear to be disputes of fact as to how “views” are tallied on Facebook. As such, this aspect of the Government’s Motion will be denied. That said, the two cases the Government cites in support of its method of calculating disseminations, United States v. Dish Network L.L.C., 954

F.3d 970, 976 (7th Cir. 2020) and United States v. Reader's Dig. Ass'n, Inc., 662 F.2d 955, 966 (3d Cir. 1981), are readily distinguishable from the present case. In Dish Network, violations were based on the number of telephone calls made. 954 F.3d at 976. The court in Reader's Digest found each unlawful letter in a mass mailing was a separate violation. Posting videos and radio shows on social media is entirely different than calling consumers or sending letters, however, as the latter are targeted forms of communication where the number of intended recipients is readily calculable.

To the extent the Government will ask the jury to find that Defendant Nepute violated the FTC and COVID Acts, the Court will require it to provide more pertinent and persuasive legal authority and reasoning as to what constitutes a “dissemination” for Facebook videos and emails, before the Court will instruct the jury on this issue.

C. Defendant Nepute's Motion for Partial Summary Judgment

Defendant Nepute moves for partial summary judgment as to the issue of civil penalties under the COVID-19 Act. In his Motion for Partial Summary Judgment, Defendant Nepute argues the Government is not entitled to recover civil penalties under the COVID-19 Act, because the evidence does not support a finding that he knowingly violated the Act.

To recover civil penalties for violations of the COVID-19 Act, the Government must establish Defendant Nepute acted “with actual knowledge or knowledge fairly implied on the basis of objective circumstances that such act is unfair or deceptive and is prohibited” by the COVID-19 Act. 15 U.S.C. § 45(m)(1)(A). Knowledge can be “fairly implied” where “a reasonable and prudent man under the circumstances would have known of the existence” of a statute or regulation, and “that the action charged violated that provision.” United States v. Nat'l Fin. Servs., Inc., 98 F.3d 131, 139 (4th Cir. 1996). See also Dish Network L.L.C., 954 F.3d at 978

(“Traditionally, ignorance of the law is no excuse. But [15 U.S.C.] § 45(m)(1)(A) includes a variation on an ignorance-of-the-law defense; a [defendant] can be liable only if it either knew that the act was unlawful or if it should have known the act was unlawful (‘knowledge fairly implied’).”)

Turning to the facts of this case, the COVID-19 Act was enacted on December 27, 2020. On March 30, 2021, the FTC sent a letter enclosing a copy of the COVID-19 Act to Defendant Nepute’s attorney, informing Defendant Nepute that the Act “provides that marketers who make deceptive claims about the treatment, cure, prevention, or mitigation of COVID-19 are subject to a civil penalty[.]” (ECF No. 96, Ex. 7 at 1). The Government filed suit against Defendant Nepute alleging violations of the COVID-19 Act on April 15, 2021. Defendant Nepute maintains that he had no knowledge of the COVID-19 Act prior to March 30, 2021, and he had no knowledge that he might be in violation of it prior to the filing of this lawsuit.

The Government argues Defendant Nepute’s knowledge of the COVID-19 Act is fairly implied since its enactment on December 27, 2020. Plaintiff points to the fact that in May 2020, the FTC sent a letter to Defendant Nepute stating he was unlawfully advertising that supplements Vitamin C and D can treat or prevent COVID-19. It is undisputed that Defendant Nepute was advised in this letter to review “all other claims for your products and services and immediately cease making claims that are not supported by competent and reliable scientific evidence.” (ECF No. 96, Ex. 15 at 3-4). The Government also points to the evidence that Defendant Nepute had marketed vitamins and supplements for at least a decade, and that he kept abreast of the news and participated in legislative decision-making related to Vitamin D, zinc, and COVID-19. The Government argues that a reasonably prudent person, with over a decade of experience in vitamin and supplement marketing, and who advertises on behalf of a multimillion-dollar supplement

enterprise, would have been aware of a major federal consumer protection statute implicating his business and marketing. See F.T.C. v. Bonnie & Co. Fashions, No. CIV. 90-4454 (HLS), 1992 WL 314007, at *7 (D.N.J. Sept. 28, 1992) (finding knowledge of an FTC Rule was “fairly implied” at summary judgment where, among other things, the defendant had worked in the relevant “industry her entire adult life”). The Government further argues Defendant Nepute knew or should have known that he was in violation of the COVID-19 Act at the time it was enacted, because he had been warned seven months earlier that advertisements in which he made claims that supplements were effective in treating or preventing COVID-19 violated the FTC Act, and yet Defendant Nepute ignored the FTC’s warning.

Having reviewed all the evidence in a light most favorable to the non-moving party, the Court finds Defendant Nepute is not entitled to partial summary judgment as to the issue of civil penalties. There is evidence in the record from which a jury could conclude that Defendant Nepute knew, or a reasonable person would have known, before this suit was filed, about the COVID-19 Act and that his advertisements were in violation of its provisions.

IV. Conclusion

For the reasons set out above, the Court grants the Government’s motion to exclude the testimony of two of Defendant Nepute’s experts. Dr. Parks and Defendant Nepute are not qualified to testify as experts in this case. Defendant Nepute’s expert Dr. Holick will be precluded from offering testimony as to whether Defendant Nepute’s advertisements were deceptive or misleading. As for the Government’s Motion for Partial Summary Judgment, the Court finds the undisputed evidence establishes that the publications at issue were advertisements within the meaning of the FTC Act. The Court further finds there is a lack of evidence in the record to substantiate claims that either (a) Vitamin D and/or zinc are more effective than the vaccine at

preventing COVID-19, or (b) zinc is effective for preventing and/or treating COVID-19. The Court also finds the undisputed evidence establishes that Defendant Nepute can be individually liable for Quickwork's advertising. The Government's Motion for Partial Summary Judgment is otherwise denied. Finally, the Court denies Defendant Nepute's Motion for Partial Summary Judgment because there is evidence in the record from which a reasonable jury could conclude, based on the circumstances, that Defendant Nepute knew or should have known about the COVID-19 Act and that his advertisements were in violation of its provisions.

Accordingly,

IT IS HEREBY ORDERED that the United States of America's Motion to Exclude Defendant Eric Anthony Nepute's Experts is **GRANTED** as set forth herein. [ECF No. 78].

IT IS FURTHER ORDERED that the United States of America's Motion for Partial Summary Judgment of Liability is **GRANTED in part** and **DENIED in part**. Consistent with the Court's Memorandum and Order, the motion is **GRANTED** to the extent that the Court finds the following: (1) the publications at issue on summary judgment were advertisements within the meaning of the Federal Trade Commission Act; (2) there is a lack of evidence in the record to substantiate claims that either (a) Vitamin D and/or zinc are more effective than the vaccine at preventing COVID-19, or (b) zinc is effective for preventing and/or treating COVID-19; and (3) Defendant Eric Anthony Nepute can be individually liable for Quickwork LLC's advertising. In all other respects, the motion is **DENIED**. [ECF No. 94]

IT IS FURTHER ORDERED that Defendant Eric Anthony Nepute's Motion for Partial Summary Judgment as to Civil Penalties is **DENIED**. [ECF No. 82].

A handwritten signature in black ink that reads "Ronnie L. White". The signature is written in a cursive, flowing style.

RONNIE L. WHITE
UNITED STATES DISTRICT JUDGE

Dated this 19th day of July 2023.